

**REMARKS**

Applicants submit that the amendments herein are fully supported in the present specification as filed and add no new matter (e.g., the subject matter of claims 7 and 8 have already been considered). Further, the amendments herein address issues that are first raised in the outstanding Office Action, and were not made earlier, because the first indication to Applicants that the present amendments would be needed was in that Office Action (e.g., the new prior art rejection). Therefore, entry of the present Amendment is proper, and is respectfully requested.

In the alternative, if the Examiner continues with the rejections of the present application, it is respectfully requested that the present Amendment be entered for purposes of an Appeal. The Amendment reduces the issues on appeal by reducing the number of claims (e.g., claims 7 and 8 have been canceled). Thus, the issues on appeal would be reduced.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

***Status of the Claims***

In the present Amendment, claims 1 and 3 have been amended. Also, claims 7 and 8 are presently canceled, wherein claims 4-6 were previously canceled, without prejudice or disclaimer of the subject matter contained therein. Thus, claims 1-3 are pending in the present application.

No new matter has been added by way of these amendments. Claims 1 and 3 have been amended by incorporating some subject matter of claims 7 and 8, respectively.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

*Issues under 35 U.S.C. § 103(a)*

Claims 1-3, 7 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Misaki '996 (U.S. Patent No. 4,765,996) in view of Kwak '997 (U.S. Patent No. 6,402,997) and Nanbu '675 (U.S. Patent No. 6,074,675) (see pages 2-4 of the Office Action). Applicants respectfully traverse and reconsideration is requested based on the following remarks.

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

The new rejection is different from the previous rejection in that Nanbu '675 is now cited to account for the claimed ranges of average particle diameters (0.05-0.8 µm or 0.05-0.5 µm) of the emulsifying agent-coated iron salt. However, Applicants respectfully submit that the instant

rejection is also improper. Overall, Applicants respectfully submit that the *Graham* factors weigh in Applicants' favor, and that a proper rationale has not been set forth in forming the outstanding rejections.

#### The Present Invention and Its Advantages

The present invention is directed to iron-enriched and vitamin-enriched rice or barley, wherein the rice grains or barley grains are coated with an emulsifying agent-coated iron salt composition (e.g., claims 1 and 3) or coated with a polyglycerol fatty acid ester (claim 2). Also, the pending claims recite that the iron salt has an average particle diameter of 0.05 to 0.8  $\mu\text{m}$  (claims 1 and 3) or the range of 0.05 to 0.5  $\mu\text{m}$  (claim 2). Further, as recited in claims 1 and 3, the emulsifying agent is an enzymatically decomposed lecithin. The present invention achieves unexpectedly less loss of, for example, vitamins and minerals upon storage of the rice or barley.

#### Evidence of Record

On December 8, 2008, Applicants submitted a Declaration pursuant to 37 C.F.R. § 1.132 by co-inventor Noboru SAKAGUCHI. In the Rule 132 Declaration, four different examples were prepared (i.e., "Enriched Rice 1-4"). Applicants respectfully submit the following explanation as the Rule 132 Declaration is applicable to the new rejection.

As described at pages 2-3 of the Rule 132 Declaration, "**Enriched Rice 1**" was prepared in accordance with Example 5 of Misaki '996. As a comparison to Enriched Rice 1, "**Enriched Rice 2**" was also prepared in accordance with Example 5 of Misaki '996, except the aqueous suspension containing ferric pyrophosphate was replaced with an emulsifying agent-coated iron salt composition as described in Example 1 of Applicants' specification. Enriched Rice 2

represents the present invention. Also, “**Enriched Rice 3**” was prepared in the same way as Example 8 of Applicants’ specification, but carried out using the vitamins and minerals according to Example 5 of Misaki ‘996 (using the aqueous suspension containing ferric pyrophosphate). As a comparison to Enriched Rice 3, “**Enriched Rice 4**” was prepared in the same way as Enriched Rice 3 except the aqueous suspension containing ferric pyrophosphate of Misaki ‘996 was replaced with an emulsifying agent-coated iron salt composition as described in Example 1 of Applicants’ specification. In other words, Enriched Rice 4 represents the present invention.

With these four examples, three different tests were conducted which measured: (1) residual ratio (%) of vitamins and minerals in the product, which is the finally prepared enriched rice (see Table I); (2) the percentage (%) of loss after washing the enriched rice (see Table II); and (3) residual ratio (%) after a one-month storage of the product (see Table III).

**Table I** on page 4 of the Rule 132 Declaration clearly shows that Enriched Rice products **2** and **4** (representing the present invention that utilizes an emulsifying agent-coated iron salt composition) have higher content of vitamins and iron, versus the comparative examples (Enriched Rice products **1** and **3**) (representing Misaki ‘996 that uses an aqueous suspension containing ferric pyrophosphate). For instance, Enriched Rice **2** has a significantly higher residual ratio of 69.0% versus the 29.8% of Enriched Rice **1**.

Similarly, **Table II** shows unexpected results for the present invention. **Table II** contains data for percent loss of vitamins and minerals after washing the rice. Both Enriched Rice **2** and **4** (utilizing the emulsifying agent-coated iron salt composition) have lower loss percentages of vitamins and minerals than the comparative examples of Enriched Rice **1** and **3**. Less vitamins and minerals are lost upon washing the rice with the present invention.

Likewise, **Table III** shows unexpected results for the present invention. **Table III** contains data for percent loss of vitamins and minerals after being stored for one month. Both Enriched Rice **2** and **4** have higher residual ratios (%) of vitamins and minerals than the comparative examples of Enriched Rice **1** and **3**. The present invention has achieved excellent storage stability.

The Instant Rejection Has Been Overcome With the Evidence of Record

As explained, the present invention achieves better retention of vitamins and minerals while exhibiting improved storage stability. The excellent effects are obtained because a reaction generated by a direct contact of iron and vitamins is controlled in the present invention by using an emulsifying agent-coated iron salt composition. Thus, the Rule 132 Declaration is proper and sufficient to show patentability for the instantly claimed invention.

With regard to the new rejection of the combination of Misaki '996, Kwak '997 and Nanbu '675, the present invention has achieved unexpected results for the present invention as shown in the previously submitted Declaration. Such unexpected results are applicable to the claims as instantly amended.

In the Office Action at page 2, the Examiner states that Misaki '996 does not teach the coating of the iron salt with an emulsifying agent as instantly claimed. Applicants respectfully submit that Example 5 of Misaki '996 as reproduced in the Rule 132 Declaration is the closest prior art example. This is because the reproduced example in the Declaration is rice coated with ferric pyrophosphate (see, e.g., column 9, about line 46 of Misaki '996). Applicants also note the amendments to the claims as shown herein. The present invention is defined as at least an enzymatically decomposed lecithin that is used as the emulsifying agent. Applicants also note

that the Misaki '996 embodiment (e.g., see Enriched Rice 1 or 2 of the Rule 132 Declaration) leads to higher losses of vitamins and minerals, whether such losses are measured when the product was made, after washing, and after storage for one month. And again, Misaki '996 is prepared using iron alone.

No mention is made with respect to the previously filed Rule 132 Declaration (as the instant rejection is new in view of a new combination of references). Accordingly, Applicants respectfully request reconsideration of all arguments and evidence to date.

Further, although evidence of unexpected results must compare the claimed invention with the closest prior art, the patent applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art. See *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966). As stated in *Geiger*:

Applicant compared his system with the most relevant prior art. It is not required that the claimed invention be compared with subject matter that does not exist in the prior art. The applicant is not required to create prior art, nor to prove that his invention would have been obvious if the prior art were different than it actually was.

2 USPQ2d at 1279 (Applicants' emphasis added).

In other words, Applicants only have to reproduce an example of, e.g., Misaki '996 instead of a combination of, e.g., Misaki '996 + Kwak '997 or Misaki '996 + Kwak '997 + Nanbu '675. Thus, the testing in the Rule 132 Declaration is sufficient.

Further, as relevant to the instant situation, as stated in *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976):

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. \* \* \* An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence

then be evaluated only on its knockdown ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. **Prima facie obviousness is a legal conclusion, not a fact.** Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. \* \* [A] final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

(Emphasis added.)

For the present situation, Applicants request that the previous Rule 132 Declaration be reconsidered as applicable to the new rejection, and that it is not evaluated against the conclusion itself, rather be judged against the facts on which the conclusion was based.

#### Other Distinctions

The cited primary reference of Misaki '996 fails to disclose or suggest the enriched rice or barley having an emulsifying agent-coated iron salt composition, wherein the iron salt has an average particle diameter of 0.05-0.8 µm or 0.05-0.5 µm as instantly claimed. Also, Kwak '997 and Nanbu '675 do not properly account for the deficiencies of the primary reference and are improperly combined with the primary reference.

As mentioned and as can be seen from the Rule 132 Declaration, the Misaki '996 embodiment leads to higher losses of vitamins and minerals, whether such losses are measured when the product was made, after washing, and after storage for one month. And again, Misaki '996 is prepared using iron alone.

Additionally, Applicants note that in the case that an average particle diameter of the iron salt is more than 2 µm, rice or barley of which surface is uniformly coated cannot be obtained

(see the present specification at page 8, lines 15-18). Thus, the present invention has unexpected advantages with the recited ranges.

Besides the above mentioned unexpected results, the cited references are not properly combined. Kwak '997 actually disclose an emulsifier-coated iron salt composition as stated by the Examiner. The emulsifier that is used in Kwak '997, however, is polyglycerol fatty acid esters (PGMS) (see column 3, lines 15-41), and an enzymatically decomposed lecithin as instantly claimed is not disclosed. More importantly, Kwak '997 discloses iron-coating microcapsules of 2-5  $\mu\text{m}$  (see column 3, lines 53-56), i.e., rather large particles, of which use is to be mixed with beverages such as milk or juice (see column 2, lines 47-50 and Test Examples), and not for coating the surface of rice.

In contrast to references like Kwak '997, in the present invention, an emulsifying agent-coated iron salt composition is used for coating the surface of rice or barley so that particle size should be smaller (i.e., preferably 0.05 – 2  $\mu\text{m}$ ; see page 13, lines 1-6). That is, large particles having a particle size of 2-5  $\mu\text{m}$  as in Kwak '997 would not be suitable for coating. This makes the references inconsistent with the present invention. Applicants note that any cited reference used for a rejection under 35 U.S.C. § 103(a) must be considered in its entirety, i.e., as a whole, including those portions that would lead away from a claimed invention. See *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). This includes anything inconsistent with the present invention.

Accordingly, one of ordinary skill in the art would not combine Misaki '996 with Kwak '997, and then further with Nanbu '675. Kwak '997 does not teach to apply its microcapsules to coating. Also, one of ordinary skill in the art would not have the proper rationale or motivation

to use the iron-coating microcapsules of 2-5  $\mu\text{m}$  of Kwak '997 instead of the iron salt of Misaki '996 for the reasons stated above.

Based on the above and the evidence of record, Applicants respectfully submit that a proper weighing of the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue and any evidence of secondary considerations, resides in Applicants' favor. *Graham; supra*. Reconsideration and withdrawal of this rejection are respectfully requested.

### ***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: March 30, 2010

Respectfully submitted,

By   
**GARTH M. DAHLEN**  
USPTO #43,575  
Gerald M. Murphy, Jr.  
Registration No.: 28977  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Road, Suite 100 East  
P.O. Box 747  
Falls Church, VA 22040-0747  
703-205-8000